K072370
pg 1 of 3

SURGICRAFT

510 (k) Summary

JUL 24 2008

A	510(k) Owner	Surgicraft Limited 16 The Oaks Clews Road Redditch, Worchester England B98 7ST
	Contact	Donald W. Guthner Orgenix, LLC 111 Hill Road Douglassville, PA 19518 (646) 460-2984 (484) 363-5879 (FAX) dg@orgenix.com
	Preparation Date	July 12, 2008
B	Trade Name	*Surgicraft Surgical Mesh System* consists of the: • Surgical Mesh sizes 4 to 20cm (ACM###); • Surgical Mesh sizes A to D (RCM###); • Surgical Containment Mesh sizes 1 to 4 (GCM###);
	Common Name	Surgical Mesh
	Classification Name	Polymeric Surgical Mesh (21 CFR 878.3300, Product code FTL)
C	Predicate Device(s)	K053215 – NuVasive Surgical Mesh System K070961 – Biomerix Surgical Mesh
D	Device Description	The *Surgicraft Surgical Mesh System* consists of a series of specialized shapes of surgical mesh made from commercially available polyester suture fibers. All sizes incorporate regions of reinforced holes to assist secure anchoring of the mesh to tissue. The devices are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

E	Intended Use	The *Surgcraft Surgical Mesh* is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery. The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair.
F	Technological Characteristics	As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States. Engineering drawings, labeling, laboratory and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

G	Non-Clinical Testing	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.
		• Biocompatibility testing according to ISO 10993
		  ○ NAMSA reference T1261 300 Max Sensitization extract 0.9% sodium chloride
		  ○ NAMSA reference T1261 300 Max Sensitization extract sesame oil
		  ○ NAMSA reference V0023 221 Genotoxicity dimethyl sulfoxide extract
		  ○ NAMSA reference V0023 221 Genotoxicity 0.9% sodium chloride extract
		  ○ NAMSA reference T1250 802 Muscle Implantation study – 4 weeks
		• Toxicity was tested according to Directive 93/42/EC, EN ISO 1099-1 FDA
		• Cytotoxicity, L 929-Proliferation was tested according to EN ISO 10993-5, -12, EN ISO 9363-1, LM SOP 4-06-01
		• Chemical Analysis (characterization of organic leachables) was tested according to EN ISO 10993-1, -12, -18, LM P 8-01, LM SOP 9-01-01

K072370
pg 3 of 3

- Mechanical Testing
  - Dynamic Tensile Fatigue
  - Static Tensile
  - Burst Strength
  - Suture Attachment Strength
  - Screw Pullout Strength
  - Tear Resistance
  - Screw Resistance.

H	Clinical Testing	Not applicable to this device
I	Conclusions	Based on the 510(k) Summary and the information provided herein, we conclude that the *Surgicraft Surgical Mesh System* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
J	Additional Information	The *Surgicraft Surgical Mesh System* is not a kit. Each sterile single-use implantable mesh device will be packaged separately. Each non-sterile reusable instrument and instrument case will be packaged separately

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2008

Surgicraft Ltd.
% Orgenix, LLC
Mr. Donald W. Guthner
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K072370
Trade/Device Name: Surgicraft Surgical Mesh System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 30, 2008
Received: July 31, 2008

Dear Mr. Guthner:

This letter corrects our substantially equivalent letter of July 24, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072370

Indications for Use

510(k) Number (if known): K072370

Device Name: Surgicraft Surgical Mesh System

Indications For Use:

The Surgcraft Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery.

The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072370